

### **REMARKS**

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

#### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-19 are pending in this application. In order to expedite prosecution, claim 1 has been amended to include an additional precursor process step which is supported in the specification, e.g., at paragraphs [0016-0018] and [0060] in the publication of this application. New claims 18 and 19 have been added for different embodiments of the invention. No new matter has been added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

#### **II. THE OBJECTIONS TO THE CLAIMS HAVE BEEN OVERCOME**

The objections to claims 1-8 have been overcome in light of the following amendments and/or arguments:

#### **III. THE 35 U.S.C. 112, 1<sup>st</sup> PARAGRAPH REJECTION HAS BEEN OVERCOME**

Claims 1-8 were rejected as allegedly lacking enablement for the full scope of the claimed invention. The applicants request reconsideration of this rejection for the following reasons.

The claims were rejected as allegedly failing to be enabling for the making of solvates (specifically with regard to process step (b2) - converting the resulting compound (III) with a cyanate into the isocyanate of the formula (V) or a solvate thereof).

However, rejection appears to confuse quantity of experimentation with undue experimentation, i.e. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation

should proceed.” *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Time and expense are merely factors in this consideration and are not the controlling factors. *United States v. Teletronics Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989). *See also MPEP 2164.06.*

As noted in “Solid-State Chemistry of Drugs”, second edition, Bryn et al., SSCI, Inc. page 244 (1999), it is common practice in the pharmaceutical industry to use mixtures of solvents for the crystallization of a drug and that because many drugs can form multiple solvates, the use of mixed solvent solutions can greatly multiply the probability of obtaining a crystal solvate.

Given the similarity in synthesis of pharmaceutical drugs and agrochemical compounds, one of ordinary skill in the art would ascribe the formation of solvates to agrochemicals as well, i.e. one of ordinary skill in the art would be able to make compound (III) or a solvate thereof and would be able to determine whether a solvate had indeed been formed. The state of the art is such that a great deal of experimentation is to be expected and as such would not constitute undue experimentation by one of ordinary skill in the art.

#### **IV. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME**

Claims 1-8 were rejected as allegedly being obvious by Vermehren et al. (DE 199 463 41, -“Vermehren” (parallel to US 7,026,477))<sup>1</sup> in view of Stubbs (American Chemical Journal, 50, pp 193-204, (1913) -“Stubbs”). The applicants request reconsideration of this rejection for the following reasons.

With the added process step in amended claim 1, all elements of the applicants’ claimed invention have not been taught or suggested by the combination of Vermehren and Stubbs with the common knowledge to those of skill in the art and therefore, the applicants’ claims are unobvious for this reason alone.

However, even if the applicants had not amended claim 1, the claims would not have been obvious for the reasons previously proffered. The applicants’ previous arguments against the combination of Vermehren and Stubbs was an allegation that there was a design need or

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<sup>1</sup> The Vermehren reference is parallel to WO 01/23368 which was referenced in the applicants’ specification (see paragraphs [0016], [0052] and [0069] of the publication of this application)

market pressure to solve a problem and that there was a finite number of predictable solution. However, no evidence was provided for the design need or market conditions alluded to in the Office Action.

Moreover, "[a] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." *In re Spinnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969). However, "discovery of the cause of a problem . . . does not always result in a patentable invention. . . . [A] different situation exists where the solution is obvious from prior art which contains the same solution for a similar problem." *In re Wiseman*, 596 F.2d 1019, 1022, 201 USPQ 658, 661 (CCPA 1979) (emphasis in original). *See MPEP 2141.02*. None of these situations apply to the combination of Vermehren and Stubbs.

Neither Vermehren nor Stubbs recognized the problem to be solved, i.e. an enhanced process for the making of the compounds of formula (I), which was reiterated in the applicants' background of the invention (see paragraphs [0016]-[0016]). Nor would one of ordinary skill in the art, without the applicants' claims to act as the answer key, have recognized that the precursor step a would have served as a solution to the problem. One of ordinary skill in the art at the time the applicants' invention was made could have tried any number of precursor steps instead of Stubbs to solve the problem which collectively does not represent a finite number of solutions to the problems. The Stubbs reference, published in 1913, unsurprisingly does not speak to the question of improving the yield of compounds of formula (I). The solution to the problem was only revealed upon the submission of the present application.

Therefore, the combination of Vermehren and Stubbs also did not render the applicants' claimed invention to be obvious for the claims unamended from the previous Office Action.

#### **V. THE OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION HAS BEEN OVERCOME**

Claims 1-8 have been provisionally rejected under obviousness-type double patenting over claims 1-20 of US 7,026,477 (Vermehren) in view of Stubbs.

MPEP 804, section III (Contrast Between Double Patenting Rejection and Rejections Based on Prior Art) states in part "...[r]ejections over a patent or another copending application based on double patenting or 35 U.S.C. 103(a) are similar in the sense that both require comparison of the claimed subject matter with at least part of the content of another patent or application, and both may require that an obviousness analysis be made. However, there are significant differences between a rejection based on double patenting and one based on 35 U.S.C. 102(e) prior art under 35 U.S.C. 103(a). *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991). One significant difference is that a double patenting rejection must rely on a comparison with the claims in an issued or to be issued patent, whereas an >anticipation or< obviousness rejection based on the same patent under 35 U.S.C. 102(e)/ 103(a) relies on a comparison with what is disclosed (whether or not claimed) in the same issued or to be issued patent. In a 35 U.S.C. 102(e)/103(a) rejection over a prior art patent, the reference patent is available for all that it fairly discloses to one of ordinary skill in the art, regardless of what is claimed. *In re Bowers*, 359 F.2d 886, 149 USPQ 570 (CCPA 1966).

While the use of secondary references are not absolutely precluded from use in an obviousness-type double patenting rejection, such uses are restricted to *In re Schneller*-type rejections and for clarification purposes. However, this is not how the Stubbs reference is being used here, i.e. the Stubbs reference is being used to address a deficiency of the Vermehren claims after making the claim to claim comparison relied upon to assert obviousness-type double patenting and as such has not been limited to a claim to claim comparison between the pending claims and the Vermehren reference. Therefore, this rejection has been made in error and should be withdrawn.

**CONCLUSION**

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,  
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By:

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